REMARKS

Amendments to the Claims

Applicants have amended claim 1 to recite an "isolated" nucleic acid. Support for the amendment may be found, e.g., on page 10, lines 1–24 and page 12, lines 3–5. Applicants have also amended claim 1 to improve its form.

Applicants have amended claims 14, 15, 32, 34 and 42–43 to cancel non-elected subject matter.

Applicants have further amended claim 15 to recite a "diagnostic composition for the diagnosis of cancer." Support for the amendment may be found, e.g., on page 20, lines 19–27 and page 27, lines 1–8 of the specification as filed.

Withdrawn Objections and/or Rejections

Applicants appreciate Examiner's withdrawal of the objection to the title and the objection to the specification for not being in compliance with the sequence rules in view of the amendments filed in the March 19, 2002 Response to Office Action ("the Response"). Applicants also appreciate Examiner's withdrawal of the objections to clams 1 and 8 in view of the amendments filed in the Response.

Applicants appreciate the Examiner's withdrawal of the rejection under 35 U.S.C. § 102(b) of claims 1, 3–9 and 10 and the rejection under 35 U.S.C. § 112, first paragraph, of claims 1–10, 14, 15 and 32 in view of the Response.

The Objections

The Examiner has objected to former claims 6–10, 14, 32 and 34–44 for depending from a rejected base claim. As indicated above, claim 1 has been

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amended to overcome the rejection (*see* below). Accordingly, applicants request that the objection to claims 6–10, 14, and 32 and 34–44 be withdrawn.

The Examiner has objected to former claims 14, 15, 32, 34 and 42–44 because they encompass non-elected inventions. As discussed above, applicants have amended claims 14, 15, 32, 34 and 42–44 to cancel subject matter that relates to non-elected inventions. As such, applicants respectfully submit that the objection should be withdrawn.

Rejections under 35 U.S.C. § 101

The Examiner has rejected former claims 1 and 3–5 under 35 U.S.C. § 101, for being directed to non-statutory subject matter. Applicants have amended claim 1 to recite an "isolated" nucleic acid. Claims 3–5 depend from claim 1 and therefore incorporate the limitation of this claim. Accordingly, applicants request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected former claim 15 under 35 U.S.C. § 112, first paragraph, for not being enabled by the specification. Specifically, the Examiner alleges that there is no enabling discussion or working examples disclosed in the specification as how to or what disease is related to the *eag* K+ channel, and that practicing the full scope of the invention would require undue experimentation. Further, the Examiner contends that "diagnosis of a disease requires proper identification of the disease being diagnosed, rather than, for example, any diseases related to cellular proliferation." *See* page 5, lines 20–21 of instant Office Action. Applicants traverse.

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Contrary to the Examiner's assertion, a diagnostic composition does not require that the composition be used for diagnosis of a specific disease. One definition of diagnose is "to analyze the cause or nature of," *e.g.*, of a problem (def. 2, Merriam–Webster's Collegiate Dictionary, 10th Ed. (1999), hereinafter Merriam–Webster's. Further, one definition of diagnosis is an "investigation or analysis of the case or nature of a condition, situation, or problem" (def. 3a, Merriam–Webster's). The specification does not contradict this definition. Thus, the composition of claim 15 can be used for diagnosis because it can be used for the analysis of a cause of a condition—*e.g.*, excessive cellular proliferation or undesired expression or over-expression of the nucleic acid molecule of the invention. Applicants have clearly demonstrated that the claimed composition can be used to identify ongoing or increased cellular proliferation (*see, e.g.,* page 20, lines 18–21 of the specification and the declaration of Dr. Pardo-Fernandez). Thus, applicants have clearly enabled the diagnostic composition of claim 15.

However, to expedite prosecution, applicants have amended claim 15 to recite a diagnostic composition for the diagnosis of cancer.

The application teaches that methods of this invention can be used to diagnose cancer such as breast cancer, neurodegenerative diseases, or psoriasis (e.g., page 27, lines 1–8 of the specification as filed). Further, the application discloses that the quantitative and qualitative analyses of the expression level of human *eag* can be indicative of, e.g., cancer, psoriasis and neurodegenerative diseases (page 12, lines 26–31 of the specification).

The application also teaches that the diagnostic compositions of the invention may be used employing methods that are well-known in the art. These include, *e.g.*, Northern blotting for the assessment of the level of mRNA or the analysis of tissue by microscopic techniques using antibodies that specifically

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recognize the polypeptide of the invention (e.g., page 27, lines 10–13). Further, the application exemplifies the use of techniques known in the art, such as RT-PCR, to evaluate the expression of the *eag* of this invention in diseased or normal cells or tissues (e.g., page 31, lines 15–19; Figure 15; Example 2). Accordingly, one of ordinary skill in the art could diagnose a disease, for example, by determining the level of *eag* nucleic acid and/or protein expression in a normal tissue and a tumor tissue, and compare the values obtained therefrom. Based on the teachings of the specification, one of ordinary skill in the art would know how to diagnose cancer according to this invention using the diagnostic compositions of the application and the methods of the application.

To further demonstrate this point, Dr. Pardo-Fernandez and his colleagues performed studies using diagnostic compositions of this invention on normal and cancerous tissue according to the methods described in the specification. As discussed in paragraphs 9–16 of the declaration of Dr. Pardo–Fernandez, they measured the levels of *eag* RNA expression in normal tissues or breast tissue from primary tumor biopsies using a diagnostic composition comprising nucleic acid molecules of this invention and reverse transcriptase PCR (RT-PCR). They demonstrated that *eag* RNA is overexpressed in neoplastic mammary gland tissue taken from mammary tumor biopsies compared to normal mammary gland tissue or tumor-free tissue of breast cancer biopsy specimens. This data supports the use of diagnostic compositions of this application in the diagnosis of diseases.

In view of the amendments to claim 15 and the above remarks, applicants respectfully request that the rejection be withdrawn.

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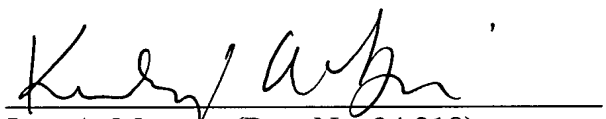
Conclusion

In view of the foregoing, applicants request allowance of pending claims 1, 3–10, 14, 15, 32 and 34–44. To expedite prosecution, applicants invite the Examiner to telephone the undersigned to discuss any matter that may be handled over the telephone.

Respectfully submitted,



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